



Billing Code: 4160-90-P
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment from the Fresenius Medical Care PSO, LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008, 73 FR 70732-70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for

any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from the Fresenius Medical Care PSO, LLC of its status as a PSO, and has delisted the PSO accordingly. The Fresenius Medical Care PSO, LLC submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on January 6, 2017.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.ahrq.gov/listed>.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: pso@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the Fresenius Medical Care PSO, LLC, a component entity of Fresenius Medical Holdings, Inc., PSO number P0081, to voluntarily relinquish its status as a PSO. Accordingly, the Fresenius Medical Care PSO, LLC was delisted effective at 12:00 Midnight ET (2400) on January 6, 2017. AHRQ notes that the Fresenius Medical Care PSO, LLC submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent to the PSO on December 12, 2016.

Fresenius Medical Care PSO, LLC has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO. In addition, according to sections 3.108(c)(2)(ii) and 3.108(b)(3) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.ahrq.gov>.

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Acting Director

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